

United States Department of the Interior

U.S. FISH & WILDLIFE SERVICE
AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP PROGRAM
4050 BRIDGER CANYON ROAD
BOZEMAN, MT 59715
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August 13, 2008

Dr. Donald Prater
Acting Director, Division of Therapeutic Drugs
for Food Animals
Document Control Unit, HFV-199
Center for Veterinary Medicine
7500 Standish Place, MPN-2
Rockville, MD 20855

Dear Dr. Prater:

The purpose of this letter is to request that CVM, on behalf of the U. S. Fish and Wildlife Service (Service), establish a Public Master File (PMF) for the use of oxytetracycline (OTC) as a medicated feed treatment to control mortality caused by bacterial pathogens in a variety of fish species. We also request that the attached information be placed in the PMF. The purpose of the Service's PMF will be to serve as a repository for efficacy and safety information and data required to support a sponsor's New Animal Drug Application (NADA) for oxytetracycline-medicated feed. All information and data, including Freedom of Information (FOI) Summaries, that are being submitted to the PMF have been reviewed by CVM and issued Technical Section complete letters or "acceptance" letters.

This submission includes three copies each of (1) an efficacy protocol, (2) abstracts from four effectiveness final study reports summarizing the use of 3.75g oxytetracycline-medicated feed per 100 pounds of fish per day for 10 consecutive days to control mortality in coho salmon and steelhead trout, (3) a CVM accepted justification to consider studies that demonstrate drug efficacy on freshwater-reared steelhead trout or rainbow trout be sufficient to satisfy the effectiveness requirements for all freshwater-reared *Oncorhynchus mykiss*, (4) CVM correspondence related to the completion of the effectiveness Technical Section from the Service's INAD file # 009006, (5) a hazard characterization document entitled: "Safety Assessment of the Microbiological Effects on Bacteria of Human Concern for Oxytetracycline Type A Medicated Feed (INAD 9332)" which addresses Section IV of the Agency's Guidance Document #152, and (6) CVM correspondence related to the acceptance of the above-mentioned hazard characterization document to satisfy the Microbial Food Safety portion of the Human Food Safety Technical Section. Also included is a FOI summary of these data, as well as the Table of Contents for the PMF. An electronic copy of all attachments is provided for your convenience.

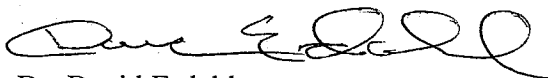
We request that the availability of this information and these data be announced in the FEDERAL REGISTER so that a commercial sponsor may use them by reference to support these components of an NADA.

The information in this PMF supports the following label claim:

For use to control mortality caused by coldwater disease associated with Flavobacterium psychrophilum in freshwater-reared salmonids and columnaris disease associated with Flavobacterium columnare in freshwater-reared Oncorhynchus mykiss. Treat fish one time per day at 3.75g/100 lbs of fish for 10 consecutive days.

If you have questions regarding the above-described request, please contact Dr. David Erdahl, Branch Chief, U. S. Fish and Wildlife Service, AADAP Program at (406)-994-9904. We would like to thank you in advance for your time and consideration with respect to our request.

Sincerely,



Dr. David Erdahl
Branch Chief, AADAP Program

Attachments (3 copies of each)

1. PMF Table of Contents
2. Protocol
 - a. Efficacy of oxytetracycline-medicated feed to control mortality caused by Flavobacteriosis in a variety of fish species
3. Efficacy Final Study Reports
 - a. Abstract- Efficacy of oxytetracycline-medicated feed to control mortality of juvenile steelhead trout *Oncorhynchus mykiss* caused by columnaris, (causative agent *Flavobacterium columnare*) (Study Number BOZ-98-OTF Study #1)
 - b. Abstract- Efficacy of oxytetracycline-medicated feed to control mortality caused by columnaris, causative agent *Flavobacterium columnare*, of juvenile steelhead trout *Oncorhynchus mykiss* (Study Number BOZ-98-OTF-02)
 - c. Abstract- Efficacy of oxytetracycline-medicated feed to control mortality of fingerling coho salmon (*Oncorhynchus kisutch*) caused by coldwater disease (Study Number BOZ-98-OTF-03)

- d. Abstract- Efficacy of oxytetracycline-medicated feed to control mortality of juvenile steelhead trout *Oncorhynchus mykiss* caused by columnaris, causative agent *Flavobacterium columnare* (Study Number BOZ-98-OTF-04)
4. Report entitled: "Justification to consider studies that demonstrate drug efficacy on freshwater-reared steelhead trout or rainbow trout be sufficient to satisfy the effectiveness requirements for all freshwater-reared *Oncorhynchus mykiss*."
5. CVM correspondence related to efficacy Technical Section completion
6. Hazard characterization document entitled: "Safety Assessment of the Microbiological Effects on Bacteria of Human Concern for Oxytetracycline Type A Medicated Feed (INAD 9332)."
7. CVM correspondence related to acceptance of microbial food safety assessment
8. Freedom of Information (FOI) Summary